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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,298	05/24/2005	Andreja Vukmirovic	BPG-32983A/LEK	9220

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,298	VUKMIROVIC ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of species pluronic F68 as the poloxamer polyol, glycerol as the polyhydric alcohol and NaCl as the isotonifying agent in the reply filed on 6/29/07 is acknowledged. The traversal arguments were addressed in the non-final office action dated 9/18/07.

Applicant's amendment to claims in the response filed on 2/19/08 has been acknowledged.

Claims 1, 2 and 4-20 are pending.

Claims 1, 2 and 4-20 are examined on the merit.

Any objections and rejections made in the office action dated 9/18/07 and not specifically mentioned here are considered withdrawn.

Withdrawn Rejections

Double patenting

Applicant's submission of terminal disclosure over copending application 10521296 necessitated the withdrawal of non-statutory obvious type double patenting rejection.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/87329 of Papadimitriou as stated in the office action dated 9/18/07 and as reiterated below. Please note that applicants arguments have been addressed at the end of the reiterated rejection.

In the instant application, applicants claim a stable pharmaceutical composition of erythropoietin (EPO), wherein the composition comprises:

a. a therapeutically effective amount of EPO

b. a pharmaceutically acceptable pH buffering system,

c. a poloxamer polyol, and

d. a polyhydric alcohol.

Papadimitriou teaches an aqueous pharmaceutical composition of erythropoietin (EPO) in a pharmaceutically acceptable buffer with a pH range 5.5-7 (claims 1 and 2 of the cited reference) comprising 10-10000 μg/ml of EPO (page 22, lines 4-6) 3% of mannitol (polyhydric alcohol), up to 0.1% of pluronic F68 (poloxamer polyol) (page 22, line 10), 10-100 mM of NaCl (page 22, line15) and 10-50 mM phosphate buffer (claims 12 of the cited reference), 10 mM methionine (other pharmaceutical excipient) thereby meets the limitations of claims 1, 3-15 and 17-20. The reference also discloses the polyhydric alcohol glycerol (claim 17 of the cited reference) there by meeting the limitation of claim 16 of the instant invention. The additives such as pluronic F68, mannitol or glycerol, NaCl, phosphate buffer and methionine are all can be chemically synthesized and hence the composition of Papadimitriou are not derived from human and/or animal origin and hence meets the limitation of claim 2. Since the composition of

Papadimitriou comprises of all the ingredients of the instant invention, and it is inherent that the composition of Papadimitriou also result in a stable pharmaceutical composition.

Therefore, the cited reference of Papadimitriou anticipates the instant invention.

Response to Arguments

Applicants argue that claim 1 as amended with transitional phrase "consisting essentially of" recited, is now **partially** closed with respect to additional components which would 'materially affect the basis and novel characteristics" of the claimed invention. Applicants further argue that the cited reference of Papadimitriou teaches the need to include an antioxidant such as methionine in any 'stable' EPO composition requires methionine in its EPO compositions and the presence of methionine would "materially affect the novel characteristics " of the composition and hence, the cited reference cannot lawfully anticipate the instant invention.

Applicant's arguments filed 2/19/08 have been fully considered but they are not persuasive. As stated by applicants, the introduction of the transitional phrase "consisting essentially of" recited, is now **partially** closed with respect to additional components. It does not completely close the claim in terms of addition or deletion of additional components. MPEP section 2105, states that "[w]ith respect to the phrase "consisting essentially of", for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." In the instant case there is no clear indication in the specification as to the basic and novel characteristics and what components should be excluded that would interfere with the basic and novel characteristics.

Moreover, the claim 1 of the cited reference does not recite that the composition should contain methionine as an antioxidant agent. It recites that "optionally one or more pharmaceutically acceptable excipients present". Also on page 41, the cited reference looked at the stability of several compositions of Peg-EPO and none of the formulation contains methionine and several compositions were stable for six months without the presence of methionine as antioxidant in the compositions. Hence, applicants argument are not persuasive and hence the rejection under 35 USC 102(b) is appropriate and maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as stated in the office action dated 9/18/07 and reiterated below. Response to applicant's arguments appear at the end of reiterated rejection.

Claim 2 recites a limitation, "wherein the composition is free of additives derived from human and/or animal origin". It is unclear from the claim as recited and the specification as disclosed the nature of these "additives". Therefore, the claim as recited is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Response to Arguments

Applicants argue that the, The meaning of this limitation is and will be reasonably and sufficiently clear to one of ordinary skill in the art. particularly in view of Applicant's specification. At page 5, the specification instructs that the term "free of additives derived from human and/or animal origin" refers to:

the condition that additives which originate from human and/or animal and which are different from EPO. such as serum albumins like HSA or BSA. are not intentionally added to the composition, or if originally present in an EPO preparation have been separated or reduced during the purification and/or isolation of EPO to an unavoidable level of traces, preferably to a level that is typically undetectable by standard analytical methods.

Accordingly, it is plain that the meaning of the limitation in question is and would be reasonably discernable to a person of ordinary skill from Applicants" specification. It simply means that a composition according to claim 2 is substantially free of any materials which originate from human and/or animal origin other than EPO. To further clarify this point, Applicants have herein amended Claim 2 to specify that the composition is substantially free of additives derived from human and/or animal origin, other than EPO. It is therefore respectfully urged that this amendment and the accompanying explanation overcomes and/or satisfactorily addresses any possible or asserted ambiguity, in the language of the claim, and that the indefiniteness rejection of Claim 2 should accordingly be withdrawn".

Applicant's arguments filed 2/18/08 have been fully considered but they are not persuasive. Applicant's argument that specification provides adequate support to the claim as recited because on page 5, the specification discloses what these additives derived from the

animal source are. Applicants further state that the claim as amended with the introduction of the term "substantially" free of any materially which originate from human and/or animal origin other than EPO is quite clear. This is not persuasive, because, the term "substantially" does not mean that the composition is free of additives derived from animal origin. The plain meaning of the term "substantially" according to website dictionary, "http://www.askoxford.com/concise_oed/substantially?view=uk" is "to a great or significant extent". Hence, it is unclear that the composition is free of animal derived additives. Moreover, the claim as recited does not identify that the animal derived additives refers to ingredients such as "albumins like HAS and BSA". By referring to specification, applicants seem to be importing critical limitations into claims that are not recited in the claims. According MPEP, section 2111.01, "Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment."

New grounds of rejections

Claim Objections

Claims 10-12, 15, 19 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case applicants amended the claims in case that does not further limit the base claim from which it depends from. For e.g.,

claim 1 recited with the phrase "consisting essentially of", claims 10-12, 15, 19 and 20 have been currently amended to recite the phrase "comprises" which has a broader scope than the base claim as recited and amended.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 10-12, 15, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as amended recites the transitional phrase "consisting essentially of". This as per the MPEP section 2105, limits the scope of the claims by excluding certain elements as stated here, "[T]he transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention". However, 10-12, 15, 19 and 20 recite the transitional phrase, "comprising" is open with respect to the elements present in claim 1. Thus, constructively the dependent claims open the scope of the base claim. It is unclear whether the claim 1 is limited in its scope as currently amended or it still encompasses additional elements as recited in the dependent claims.

Therefore, the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654